

**REMARKS**

Reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

The objection to the Abstract of disclosure is deemed to have been overcome in view of the deletion of terms such as “said particles” from the amended Abstract of the disclosure.

Lines 22-23 at page 10 of the disclosure have been reworked to achieve clarity and, accordingly, the objection thereto is deemed overcome and should be withdrawn.

Claim 36 stands rejected under 35 USC § 101 and under 35 USC § 112, second paragraph. These rejections are respectfully traversed.

In view of the amendments made to claim 36, to define a process claim, it is respectfully submitted that the rejections under § 101 and § 112, second paragraph, have been overcome and should be withdrawn.

**The prior art**

Claims 21-30 and 37 stand rejected under 35 USC § 103(a) as being unpatentable over Skelbaek et al. WO 91/17821 in view of Burger et al. US Published Application No. 2004/0037890 and Kim et al. US 6,190,722. This rejection is respectfully traversed.

The primary reference relied upon by the Examiner in fashioning his obviousness rejection is **Skelbaek**. Skelbaek teaches microparticles that contain gelatine and a flavouring agent and is concerned with the oxygen and moisture stability of particles. One of ordinary skill in the art is taught that in order to solve the problem of stability, one has to address the porosity of the formed particles. This is achieved by a special process step in a spray drying process. In addition, one of ordinary skill is also informed that controlled release can be achieved by using a wax. That is the totality of the technical teaching of Skelbaek. In sum, if one is concerned with achieving stability, he or she

would reduce the porosity of the particles by employing a spraying agent in a lower temperature spray drying process.

The secondary reference, **Burger** is also concerned with the problem of generating particles having good moisture and oxygen stability. Burger offers a very specific solution to this problem, which is the provision of a glassy carbohydrate matrix consisting of film forming carbohydrate, mono, di, or trisaccharides and maltodextrin in specifically recited amounts. These are all the ingredients which one needs to achieve the stability goals referred to above. The particles made using this glassy matrix are presumed to be stable.

**Kim** contains no disclosure with respect to the moisture and oxygen stability of microparticles. It is solely concerned with the problem of how to process encapsulation media containing fats using relatively inexpensive machinery. It is respectfully submitted that Kim is barren of any teaching that would be of any conceivable value or use to one or ordinary skill faced with the problem of how to stabilise microparticles.

#### Motivation for combining prior art documents

There is no disclosure or teaching in Skelbaek of fats, film forming carbohydrates and mono, di or trisaccharides in general or the combined effect of these ingredients on stability and controlled release. And the reason it doesn't make mention of the importance of these combinations of ingredients is precisely because its teaching is that stability can be achieved effectively by the judicious selection of process conditions in a spray-drying procedure. It also teaches that controlled release is achieved by using wax.

While Skelbaek is clearly concerned with the same problems that were addressed by Applicants in the claimed invention, its teaching is clearly *away* from the claimed invention since it discloses an altogether different solution. It teaches directly away from Applicants by providing a completely different solution. It solves the stability problem but it does so in an entirely different manner from the claimed invention.

The skilled person faced with the problem of controlling stability of microparticles would regard Skelbaek as offering an entirely plausible solution to his

problem. Skelbaek is not deficient in any way. It is submitted that it would not be credible to a skilled person that Skelbaek is only going part of the way to solving the problem as the claimed invention addresses it.

Faced with the problem of how to achieve moisture and oxygen stability, and starting from Skelbaek, one of ordinary skill would not seek out Burger as a secondary reference to ameliorate the deficiencies in the teaching of Skelbaek.

Burger is concerned with the same problem addressed by Skelbaek. But it proposes a completely different solution than that proposed in Skelbaek (and indeed in the claimed invention). Burger teaches a solution is very specifically tied up to the provision of a glassy carbohydrate matrix referred to above. Like Skelbaek, Burger offers a solution that is not deficient in any way.

What possible motivation would one or ordinary skill in the art have, when starting from Skelbaek, to combine the teaching of Burger? None whatsoever, unless the problem to be addressed is how to make an already stable microparticle even more stable. Clearly, this is unreasonable! Who, in this cost sensitive industry, is going to go to the trouble and expense of making an already stable microparticle even more stable?

Nevertheless, it is Applicants' contention that the Examiner in making this combination of references, demonstrates that the combination actually *teaches even further away from the claimed invention*. Burger teaches that a glassy matrix is all that is needed. Burger does not even mention the use of fats. So now we have to consider the teaching of two experts in the field, namely, Skelbaek and Burger, both faced with the same problem who still haven't arrived at Applicants' inventive solution. They propose two entirely different solutions to the same problem, which have nothing in common with each other or with the solution proposed in the claimed invention.

As an aside, Applicants believe it worthwhile to mention a problem with the technical teaching of Burger. The Examiner, in paragraph 11 of her Office Action, at the top of page 5, seems to consider that the maltodextrin in Burger is "a known substitute" for gelatine. Applicants do not know or understand the Examiner's basis for this

assumed knowledge, but certainly she is not permitted to use her own general knowledge. Additionally, in making this observation, Applicants wonder if the Examiner noticed that in Burger the maltodextrin can be present in an amount of 0 to 30%. Thus, Burger clearly teaches that maltodextrin may or may not be present. It is a “take it” or “leave it” excipient. Insofar as Burger clearly teaches that this is an optional ingredient, Applicants do not believe it is an equivalent to gelatine, which is an essential feature of our invention and must be present in amounts of 10 to 70%.

Applicants submit that there is no incentive to combine Burger’s teaching with Skelbaek, and even if one were to make the combination, it fails abjectly to teach the claimed invention..

In fact, the Examiner appreciates this point herself, as her argument becomes even more attenuated when she proposes to combine a third document, Kim.

Since the combination of Skelbaek and Burger fail to teach the claimed invention, the Examiner employs Kim to make her rejection more tenable. The only possible reason for using Kim as a teaching is that it mentions “fat”.

It seems as if the Examiner has only resorted to Kim in desperation solely because mention is made of the word "fat". This reference is, however, simply not concerned with the problem of stabilising microparticles. There is clearly no incentive for the skilled person to combine this document with Skelbaek and Burger. Whereas one has to accept that any inventive step analysis necessarily involves hindsight to some extent, this is acceptable to the extent that it takes into account only knowledge that was available to the skilled person at the time the invention was made. It is improper for the Examiner to glean knowledge from Applicants' disclosure, and then reconstruct Applicants' claimed invention by “cherry-picking” integers from many and varied prior art documents. This approach to combining documents betrays an unacceptable hindsight analysis and bias.

It is respectfully submitted that the claims clearly distinguish over the attenuated combination posited by the Examiner. Accordingly, since the Examiner has failed to

establish *prima facie* obviousness by a preponderance of the evidence, the rejection has been overcome and should be withdrawn.

Claims 31-35 stand rejected under 35 USC § 103(a) as being unpatentable over Skelbaek et al., Burger et al., Kim et al. as applied to claims 21-30 and 37 above, and further in view of Kramer et al. US 2,886,446. This rejection is respectfully traversed.

The disclosure of Kramer et al. is limited to the effect that bloom has on the rate of release of flavour from a gelatine matrix. It discloses nothing whatever about the effect of gelatine on stability alone or when combined with any other agents. It does not even begin to suggest the gelatine should be combined with any other ingredients to improve its stability. It does not provide any incentive to one of ordinary skill in the art to use gelatine in combination with other ingredients in order to obtain oxygen and moisture stability coupled with excellent controlled release.

Since independent claim 21, from which all the other claims depend, is deemed to distinguish over the combination of Skelbaek et al., Burger et al. and Kim et al., then claims 31-35, which depend directly or indirectly from claim 21 also distinguish over that combination of references even with the addition of Kramer et al.'s teaching, which is, in any event, no more relevant than the other references employed by the Examiner. Accordingly, claims 31-35 are also deemed to distinguish over the references employed by the Examiner and, as such, the rejection has been overcome and its withdrawal is respectfully solicited.

The timely issuance of a Notice of Allowance is respectfully requested.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

ABELMAN, FRAYNE & SCHWAB  
Attorneys for Applicant

By

  
\_\_\_\_\_  
Jay S. Cinamon  
Attorney for Applicant  
Reg. No. 24,156

666 Third Avenue  
New York, NY 10017-5621  
Tel.: (212) 949-9022  
Fax: (212) 949-9190